

APR -9 1997

K970965

510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date prepared: March 10, 1996

Submitter: Midas Rex, L. P.
3001 Race Street
Fort Worth, Texas 76111
(817) 831-4181

Contact Person: Michael Fowler
Director Regulatory Affairs

Trade (proprietary) Name: Midas Rex Motor (Midas III)

Common / Classification Name: Pneumatic Cranial Drill Motor
Regulation no. 874.4250
Product code 77 ERL
Device Classification: Class II

Predicate Device: Midas Rex III motor, attachments and accessories
Midas GS and GS20 Surgical Tool System
Midas Drill Guide Attachment
Midas Telescoping System
Dissecting tools
K962483 class II

Description of the Device: Ergonomically designed motor, 62 gram in weight, 15 mm in diameter with an overall length of approximately 10.25 centimeters. The Midas Rex III motor operates at variable speeds from 25 to 70 thousand rpm's. Operating pressures range from 20-150 psi (2-10 bar), with a suggested operating pressure of 100-psi (6.9 bar) and approximately 60 thousand rpm. The Midas Rex III has a standard quick disconnect GS dissecting tool and tube attachment system, which includes a fixed or rotating footed attachment, the telescoping micro systems, and the micro mini drill guide attachment.

Statement of Intended Use:

The Midas Rex III pneumatic motor is designed for used in Ear, Nose and Throat, Otolaryngology and Maxillofacial specifications.

Technological Characteristics:

The Midas Rex III motor, attachments and accessories have the same technological characteristics (i.e., design, material, energy source) as the predicate devices.